ABBOTT

Global Medical Services

Postmarketing Safety
Dept. R422, AP34-2S
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-6008

No Adverse Event Memo
Re: Synthroid
AAD: 19 Apr 2005

Date: 22 Apr 2005

On 19 Apr 2005, a phone call was received from a consumer's relative regarding LEVOTHYROXINE SODIUM [redacted]). After speaking with [redacted] during a follow-up phone call made on 21 Apr 2005, there was not an adverse event that occurred with an Abbott Labs product. The consumer' relative was switched from an Abbott Labs SYNTHROID product to a LEVOTHYROXINE SODIUM product manufactured by [redacted] in Jan 2005. In Feb 2005, the consumer experienced an adverse event coincident with the LEVOTHYROXINE SODIUM product manufactured by [redacted]. On 21 Apr 2005, a letter to [redacted] informing them of the adverse event was sent.

Lisa M. Unda R.N.
Medical Safety Analyst

Pamela Rieb
Post-Marketing Safety Manager

CONFIDENTIAL

ABBOTT

Global Medical Services

Abbott Laboratories
Global Medical Services
200 Abbott Park Road AP34-2
Abbott Park, Illinois 60064-6186
Office: 1-800-633-9110
Fax: 1-847-938-0644

April 21, 2005

[redacted]

To Whom it May Concern;

Abbott Laboratories has received an adverse event report in which your product, LEVOTHYROXINE SODIUM®™, was identified as a suspect drug. The reporter was a relative of the consumer whose name is [redacted]. The reporter can be contacted by telephone or mail. The telephone number [redacted]. The address [redacted], [redacted]. The consumer is a [redacted] with a history of obsessive-compulsive behavior, schizophrenia, and increased blood pressure. The consumer began LEVOTHYROXINE SODIUM 200 mcg daily in Jan 2005. The relative called to report an adverse event of increased obsessive-compulsive behavior since Feb 2005. I am forwarding this information by our company for your use in complying with the FDA regulations for the reporting of spontaneous and clinical adverse events and ICH Guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

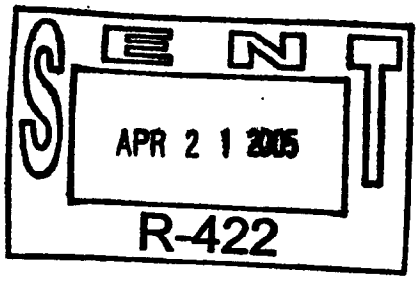
Should you wish to contact us, please call 1-800-633-9110

Sincerely,

Lisa M. Unda RN BSN

Lisa M. Unda R.N. B.S.N.

Abbott Laboratories
Medical Services Analyst
Global Pharmaceutical and Research Department



Global Medical Services, Pharmacovigilance
Global Pharmaceutical Research and Development

RECORD OF CONTACT

DATE: 4/19/04 TIME 2:19 am/pm

☑ Adverse Event

☐ AEGIS Database search

Product: Depakote/ [redacted]

Reporter Name: [redacted]

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Patient ☐ Abbott Rep* ☑ Other MOTHER

Reporter Address: [redacted]
Street
[redacted]
City State Zip

Telephone: ([redacted] [redacted] *Territory

Patient Identifiers: [redacted] Sex [redacted] Age _____ Initials

ADVERSE EVENT(S): increased obsessive/compulsive behavior

SUMMARY OF DISCUSSION:

Has a 4½ yr old daughter who was on Depakote for many, many years. Is also taking Zoloft & Navane. In January of 2005 [redacted] State Payments would not allow for Depakote to be dispensed. Was switched to [redacted] the [redacted] brand 200 mg. The mother is noticing changes in her behavior. Is becoming more obsessive in her behavior. Did not experience any changes in behavior when on Depakote. Mother is agreeable to follow-up from PMS. Contact me if you have any questions. Is not suicidal.

Name: [redacted] Date 4/19/05
Signature